

REMARKS

Claims 1-66 were examined and rejected. The claims have been amended and canceled as noted above. Re-examination and reconsideration of the claims, as amended, are respectfully requested.

The Examiner has rejected all pending claims as being anticipated by U.S. Patent No. 6,312,429 to Burbank et al. Such rejections are traversed in part and overcome in part.

While Applicants concede that the Burbank et al. '429 patent does show wire arrays which may be deployed in opposed directions and which may further be electrically energized, Applicants feel that the '491 patent falls far short of teaching each and every claim limitation in each and every claim pending in the present application.

For example, the Burbank '429 patent describes only "monopolar" energization of the wire arrays. Indeed, the structure described in the patent fails to electrically isolate the arrays so that the devices are incapable of bipolar operation. The latter point can be seen, for example, in Figs. 3 and 4 where wires 50 are carried by metal shaft 54 and wires 42 are carried by metal shaft 31. The metal shafts slide in direct engagement and are therefore not isolated. Moreover, when the wires are deployed, they also appear to be in direct contact, as shown, for example, in Fig. 10.

While the '491 patent suggests that the device may be "bipolar" (Col. 4, lines 19-33), the specific teaching is that "a return electrode (not shown)" may be placed somewhere on the device. There is no teaching or suggestion anywhere that the two wire electrode arrays may be operated in a bipolar manner, i.e. attached to opposite poles of a radiofrequency power supply.

As there is no teaching or suggestion of bipolar operation of first and second electrode arrays anywhere in the '429 patent, it is believed that independent claims 33 and 51, as well as all claims dependent thereon, are allowable over the cited art without amendment.



ROBERT S. BEHL et al.  
Application No.: 09/663,048  
Page 5

PATENT

In addition, independent claims 1 and 16 have been amended to incorporate the limitations previously set forth in claims 10 and 24, respectively, and are now also limited to electrically isolated electrode arrays and bipolar operation.

For these reasons, Applicants believe that all pending claims are now in condition for allowance and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at (650) 326-2400.

Respectfully submitted,

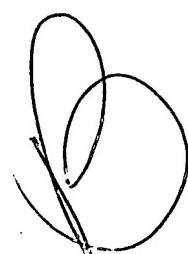
James M. Heslin  
Reg. No. 29,541

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, 8<sup>th</sup> Floor  
San Francisco, California 94111-3834  
Tel: 650-326-2400  
Fax: 415-576-0300  
JMH:jis/jke  
PA 3282349 v1



**COMPLETE SET OF PENDING CLAIMS**

1. (Twice amended) A probe for deploying electrode arrays, said probe comprising:
  - a shaft having a distal end and a proximal end;
  - a first array of electrodes mounted on the shaft to shift between a retracted configuration and a deployed configuration having a concave face;
  - a second array of electrodes mounted on the shaft at a location spaced-apart proximally from first array of electrodes, wherein the second electrode array shifts between a retracted and a deployed configuration having a concave face, wherein the first electrode array and the second electrode array are electrically isolated from each other;
  - a first connector coupled to the shaft for connecting the first electrode array to one pole of a power supply;
  - and a second connector coupled to the shaft for connecting the second array to a second pole of a power supply;
  - wherein the concave face of the first array faces the concave face of the second array when the arrays are deployed.
2. (As filed) A probe as in claim 1, wherein the first and second electrode arrays each comprise a plurality of individual electrodes which initially move axially and then evert as they are deployed.
3. (As filed) A probe as in claim 1, wherein the shaft has a self-penetrating tip.
4. (As filed) A probe as in claim 1 or 3, wherein the shaft has at least once cavity for receiving the first and second electrode arrays when retracted.
5. (As filed) A probe as in claim 1 or 3, wherein the shaft has at least one cavity for receiving the first electrode array when retracted and at least a second cavity for receiving the second electrode array when retracted.



6. (As filed) A probe as in claim 1 or 3, further comprising:  
a first rod connected to the first electrode array and slidably disposed in the shaft, wherein distal advancement of the first rod relative to the shaft causes the first electrode array to deploy distally;  
a second rod connected to the second electrode array and slidably disposed in the shaft, wherein proximal retraction of the second rod relative to the shaft causes the second electrode array to deploy proximally.

7. (As filed) A probe as in claim 1 or 3, wherein the first electrode array spans a planar area in the range between  $3 \text{ cm}^2$  to  $20 \text{ cm}^2$  when deployed, the second electrode array spans a planar area in the range between  $3 \text{ cm}^2$  and  $20 \text{ cm}^2$  when deployed, and the first and second areas are spaced-apart along a line between their respective centers by a distance in the range between 2 cm to 10 cm.

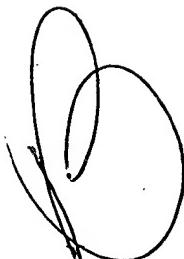
8. (As filed) A probe as in claim 1 or 3, wherein the volume between the first electrode array when deployed and the second electrode when deployed is in the range from  $30 \text{ cm}^3$  to  $150 \text{ cm}^3$ .

9. (As filed) A probe as in claim 8, wherein the volume is in the range from  $50 \text{ cm}^3$  to  $70 \text{ cm}^3$ .

Please cancel claim 10.

11. (Amended) A probe as in claim 1, further comprising a first axial conductor extending proximally along the shaft from the first electrode array to a location distal to the second electrode array, said first axial conductor being electrically coupled to the first electrode array.

12. (As filed) A probe as in claim 11, wherein the first axial conductor extends proximally beyond the proximal terminus of the first electrode array so that the



first axial conductor lies closer to the second electrode array than does any portion of the first electrode array.

13. (As filed) A probe as in claim 11, further comprising a second axial conductor extending distally along the shaft from the second electrode array to a location proximal to the first axial conductor so that a gap exists between the first and second axial conductors, said second axial conductor being electrically coupled to the second electrode array.

14. (As filed) A probe as in claim 13, wherein the second axial conductor extends distally beyond the distal terminus of the second electrode array so that the second axial conductor lies closer to the first electrode array than does any portion of the second electrode array.

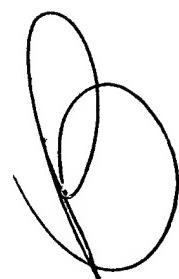
15. (As filed) A probe as in claim 13, wherein the distance between the inner termini of the first and second axial conductors is from 0.25 to 0.75 of the distance between the inner termini of the innermost portions of the first and second electrode arrays.

16. (Twice amended) A method for treating a treatment region in tissue, said method comprising:

deploying a first array of electrodes in tissue on one side of the treatment region, wherein said first electrode array has a concave face;

deploying a second array of electrodes in tissue along an axis with the first array on another side of the treatment region, wherein said second electrode array has a concave face and wherein the concave face of the first electrode array faces the concave face of the second electrode array when said arrays are deployed; and

coupling one pole of a radiofrequency power supply to the first electrode array and another pole of the radiofrequency power supply to the second electrode array



and energizing the power supply to apply electrical current between the first and second electrode arrays.

17. (As filed) A method as in claim 16, wherein deploying the first electrode array comprises introducing a first probe through tissue to a location on one side of the treatment region and advancing a first plurality of at least three electrodes from the probe in an evertng pattern.

18. (As filed) A method as in claim 17, wherein deploying the second electrode array comprises advancing a second plurality of at least three electrodes from the probe in an evertng pattern at a location on the other side of the treatment region.

19. (As filed) A method as in claim 17, wherein deploying the second electrode array comprises introducing a second probe through tissue to a location on the other side of the treatment region and advancing a plurality of at least three electrodes in an evertng pattern.

20. (As filed) A method as in any of claims 16-18 or 19, wherein the tissue is selected from the group consisting of liver, lung, kidney, pancreas, stomach, uterus, and spleen.

21. (As filed) A method as in claim 20, wherein the treatment region is a tumor.

22. (As filed) A method as in any of claims 16-18 or 19, wherein electrical current is applied at a frequency in the range from 300 kHz to 1.2 MHz.

23. (As filed) A method as in claim 22, wherein electrical current is applied at a power in the range from 50W to 300W.

Please cancel claim 24.



25. (As filed) A method as in any of claims 16-18 or 19, wherein the first and second electrode arrays each span a planar area in the range between  $3 \text{ cm}^2$  to  $20 \text{ cm}^2$ , and wherein the first and second arrays are spaced-apart along a line between their respective centers by a distance in the range between 2 cm to 10 cm.

26. (As filed) A method as in any of claims 16-18 or 19, wherein the tissue volume between the first electrode array and the second electrode is in the range from  $30 \text{ cm}^3$  to  $150 \text{ cm}^3$ .

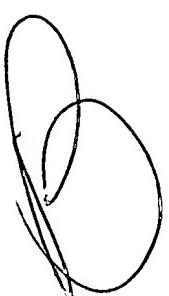
27. (As filed) A method as in claim 26, wherein the volume is in the range from  $50 \text{ cm}^3$  to  $70 \text{ cm}^3$ .

28. (As filed) A method as in any of claims 16-18 or 19, wherein said first electrode array includes a first axial conductor extending at least part of the way to the second array along the axis therebetween.

29. (As filed) A method as in claim 28, wherein the first axial conductor extends proximally beyond the proximal terminus of the first electrode array so that the first axial conductor lies closer to the second electrode array than does any portion of the first electrode array.

30. (As filed) A method as in claim 28, wherein said second electrode array includes a second axial conductor extending part of the way to the first array along the axis therebetween and wherein there is a gap between termini of the first axial conductor and the second axial conductor.

31. (As filed) A method as in claim 30, wherein the second axial conductor extends distally beyond the distal terminus of the second electrode array so that the second axial conductor lies closer to the first electrode array than does any portion of the second electrode array.



32. (As filed) A method as in claim 31, wherein the distance between inner termini of the first and second axial conductors is from 0.25 to 0.75 of the distance between the inner termini of the innermost portions of the first and second electrode arrays.

33. (As filed) A method for bipolar radiofrequency necrosis of tissue, said method comprising:

deploying a first array of electrodes in tissue on one side of a treatment region, wherein said first array has a concave face and an axial conductor extending in an axial direction from the concave face;

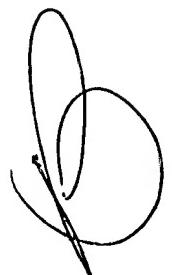
deploying a second array of electrodes in tissue on another side of the treatment region, wherein said second array has a concave face and an axial conductor extending in an axial direction opposed to the axial conductor on the first electrode array and wherein the concave face of the first array faces the concave face of the second array when the arrays are disposed, and

applying bipolar radiofrequency current to the tissue between the first and second electrode arrays.

34. (As filed) A method as in claim 33, wherein deploying the transverse face of the first electrode array comprises introducing a first probe through tissue to a location on one side of the treatment region and advancing a first plurality of at least three electrodes from the probe in a radially diverging pattern.

35. (As filed) A method as in claim 34, wherein the diverging pattern is everting.

36. (As filed) A method as in claim 34 or 35, wherein deploying the transverse second electrode array comprises advancing a second plurality of at least three electrodes from the probe in a radially diverging pattern at a location on the other side of the treatment region.



37. (As filed) A method as in claim 36, wherein the diverging pattern is everting.

38. (As filed) A method as in claim 34 or 35, wherein deploying the transverse face of the second electrode array comprises introducing a second probe through tissue to a location on the other side of the treatment region and advancing a plurality of at least three electrodes in a radially diverging pattern.

39. (As filed) A method as in claim 38, wherein the diverging pattern is everting.

40. (As filed) A method as in claims 33, 34, or 35, wherein the tissue is selected from the group consisting of liver, lung, kidney, pancreas, stomach, uterus, and spleen.

41. (As filed) A method as in claim 40, wherein the treatment region comprises a tumor lesion.

42. (As filed) A method as in claims 33, 34, or 35, wherein the bipolar radiofrequency current is applied at a frequency in the range from 300 kHz to 1.2 MHz.

43. (As filed) A method as in claim 42, wherein the bipolar radiofrequency current is applied at a power in the range from 50W to 300W.

44. (As filed) A method as in claims 33, 34, or 35, wherein applying the bipolar radiofrequency current comprises coupling one pole of a radiofrequency power supply to the first electrode array and another pole of the radiofrequency power supply to the second electrode array and energizing the power supply.

45. (As filed) A method as in claims 33, 34, or 35, wherein the transverse face of the first electrode array spans a planar area in the range between 3 cm<sup>2</sup> to 20 cm<sup>2</sup>, the transverse face of the second electrode array spans a planar area in the



range between 3 cm<sup>2</sup> and 20 cm<sup>2</sup>, and the first and second arrays are spaced-apart along an axial line between their respective centers by a distance in the range between 2 cm and 10 cm.

46. (As filed) A method as in claim 45, wherein the termini of axial conductors of the first and second electrode arrays are spaced-apart in the axial direction by a distance in the range between 0.5 cm and 5 cm.

47. (As filed) A method as in claim 33, wherein the tissue volume between the transverse face of the electrode array and the transverse face of the second electrode is in the range from 30 cm<sup>3</sup> to 150 cm<sup>3</sup>.

48. (As filed) A method as in claim 33, wherein the distance between the termini of the first and second axial conductors is from 0.25 to 0.75 of the distance between the inner termini of the innermost portions of the first and second electrode arrays.

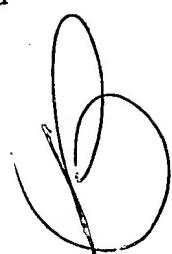
49. (As filed) A kit for treating a treatment region in tissue, said kit comprising:

a first array of electrodes which are deployable in tissue;  
a second array of electrodes which are deployable in tissue; and  
instructions for use setting forth a method according to claim 16 or 33.

50. (As filed) A kit as in claim 41, further comprising a package for holding the first electrode array, the second electrode array, and the instruction for use.

51. (As filed) A probe for deploying electrode arrays, said probe comprising:

a shaft having a distal end and a proximal end;  
a first array of electrodes mounted on the shaft to shift between a retracted configuration and a deployed configuration having a concave face; and



a second array of electrodes mounted on the shaft at a location spaced-apart proximally from the first array of electrodes, wherein the second electrode array shifts between a retracted and a deployed configuration having a concave face;

wherein the first array is electrically isolated from the second array to permit the arrays to be connected to a power supply for bipolar operation and wherein the concave face of the first array faces the concave face of the second array when the arrays are deployed.

52. (As filed) A probe as in claim 51, wherein the first and second electrode arrays each comprise a plurality of individual electrodes which initially move axially and then evert as they are deployed.

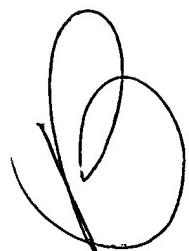
53. (As filed) A probe as in claim 51, wherein the shaft has a self-penetrating tip.

54. (As filed) A probe as in claim 51 or 53, wherein the shaft has at least once cavity for receiving the first and second electrode arrays when retracted.

55. (As filed) A probe as in claim 51 or 53, wherein the shaft has at least one cavity for receiving the first electrode array when retracted and at least a second cavity for receiving the second electrode array when retracted.

56. (As filed) A probe as in claim 51 or 53, further comprising:  
a first rod connected to the first electrode array and slidably disposed in the shaft, wherein distal advancement of the first rod relative to the shaft causes the first electrode array to deploy distally;

a second rod connected to the second electrode array and slidably disposed in the shaft, wherein proximal retraction of the second rod relative to the shaft causes the second electrode array to deploy proximally.



57. (As filed) A probe as in claim 56, wherein the first and second rods may be deployed separately.

58. (As filed) A probe as in claim 51 or 53, wherein the first electrode array spans a planar area in the range between 3 cm<sup>2</sup> to 20 cm<sup>2</sup> when deployed, the second electrode array spans a planar area in the range between 3 cm<sup>2</sup> and 20 cm<sup>2</sup> when deployed, and the first and second areas are spaced-apart along a line between their respective centers by a distance in the range between 2 cm to 10 cm.

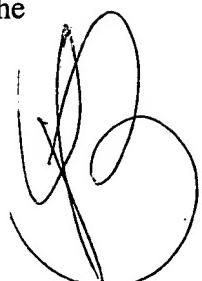
59. (As filed) A probe as in claim 51 or 53, wherein the volume between the first electrode array when deployed and the second electrode when deployed is in the range from 30 cm<sup>3</sup> to 150 cm<sup>3</sup>.

60. (As filed) A probe as in claim 59, wherein the volume is in the range from 50 cm<sup>3</sup> to 70 cm<sup>3</sup>.

61. (As filed) A probe as in claim 51 or 53, wherein the first electrode array and second electrode array are electrically isolated from each other, further comprising a first connector for connecting the first electrode array to one pole of a power supply and a second connector for connecting the second array to a second pole of a power supply.

62. (As filed) A probe as in claim 61, further comprising a first axial conductor extending proximally along the shaft from the first electrode array to a location distal to the second electrode array, said first axial conductor being electrically coupled to the first electrode array.

63. (As filed) A probe as in claim 62, wherein the first axial conductor extends proximally beyond the proximal terminus of the first electrode array so that the first axial conductor lies closer to the second electrode array than does any portion of the first electrode array.



64. (As filed) A probe as in claim 62, further comprising a second axial conductor extending distally along the shaft from the second electrode array to a location proximal to the first axial conductor so that a gap exists between the termini of the first and second axial conductors, said second axial conductor being electrically coupled to the second electrode array.

65. (As filed) A probe as in claim 64, wherein the second axial conductor extends distally beyond the distal terminus of the second electrode array so that the second axial conductor lies closer to the first electrode array than does any portion of the second electrode array.

66. (As filed) A probe as in claim 64, wherein the distance between the inner termini of the first and second axial conductors is from 0.25 to 0.75 of the distance between the inner termini of the innermost portions of the first and second electrode arrays.